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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/461,646	12/14/99	GROTENDORST	

HM12/1023

EXAMINER: G FIBED1130

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EXAMINER: G FIBED1130

PAPER NUMBER: 18

1647
DATE MAILED:

10/23/01

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 8/2/01

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-14 is/are pending in the application.
Of the above, claim(s) 6-14 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-5 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claim(s) 1-14 are subject to restriction or election requirement.

Application Papers

- ☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 4,5,9,17
- ☐ Interview Summary, PTO-413
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Part III: Detailed Office Action

Notice: Effective June 18, 2000, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit **1647**.

Restriction Requirement:

Applicant's election with traverse of Invention I, claims 1-5 in Paper No. 16 filed 8/2/01 is acknowledged. The traversal is on the ground(s) that (1)the groups of inventions are not independent, and (2) the examination of the entire application would not constitute a burden to search. This is not found persuasive because with respect to point (1) above, the inventions are distinct as noted in the last Office Action, as shown by the distinctness described therein. Applicant's attention is directed to MPEP 806.05.

1. With respect to point (2) above, contrary to applicants' assertion that any search of the prior art in regard to group I will reveal whether any prior art exists as to the other Groups, a search is directed to references which would render the invention obvious, as well as references directed to anticipation of the invention, and therefore requires a search of relevant literature in many different areas of subject matter. For example, a search for group I will not necessarily reveal any antisense nucleic acids, as the latter are defined by function, rather than structure, and may correspond to non-coding regions. With respect to group V, Applicants argue that if the proteins claimed in group I are novel over the prior art then the methods of using such are similarly novel. This argument has been fully considered but is not deemed persuasive because each independent group requires a separate search for determination of patentability, as set forth above. Applicants argument appears to be directed at the issue of consideration of method claims once patentability of the product used has been determined, under 35 U.S.C. §103(b). Applicants are advised that at such time as the elected product claim(s) are indicated as being allowable, rejoinder of claims drawn to methods of using such may be requested pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86). Such rejoinder is *not* tantamount to a withdrawal of the restriction

requirement.

The requirement is still deemed proper and is therefore made FINAL.

Formal Matters:

5 37 C.F.R. §1.821(d) states:

Where the description or claims of a patent application discuss a sequence listing that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the assigned identifier, in the text of the description or claims, even if the sequence is also embedded in the
10 text of the description or claims of the patent application.

Applicants are required to amend the specification and claims to comply with 37 C.F.R. §1.821(2)(d). Specifically, it is noted that claims 2 and 3 set forth particular regions of the sequence set forth in Figure 2, which should be referred to by reference to SEQ ID NO: 2 rather than
15 to the figure.

Correction is required.

Objections and Rejections under 35 U.S.C. §101:

20 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-5 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-
25 statutory subject matter.

The claims read on products of nature, as fragments of CTGF are known to occur in nature, as are polynucleotides encoding such. Amendment of the claims to indicate that the claimed products are isolated, purified, or to otherwise show the hand of the inventor would be remedial.

Objections and Rejections under 35 U.S.C. §112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear whether the claim is encoded to a polynucleotide which encodes only the fragment of claim 1, or whether a full-length polynucleotide is encompassed, as such would comprise a region encoding said fragment. Amendment of the claim to use a phrase such as 'encoding a polypeptide'...
10 "consisting of" or "comprising" (in the appropriate context) would be remedial.

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the
15 basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the
20 applicant for patent.

Claims 1, 3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Brigstock et al., U.S. Patent Number 5,876,730.

Brigstock et al. disclose and claim HBGF and nucleic acids encoding such; see claims 1-4. It is noted that a polypeptide beginning at amino acid residue 248 from the N-terminus of CTGF, as
25 claimed in claim 3 of Brigstock et al., would comprise exon 5 as set forth in Figure 2 of the instant application, which corresponds to residue 252. HBGF is disclosed as being mitogenic, see assay results at columns 19-21.

Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Grotendorst et al., U.S. Patent Number 5,408,040, cited by applicants.

Grotendorst discloses CTGF and nucleic acids encoding such. At column 3 lines 15-17 and 26-29, Grotendorst clearly indicates that functional fragments of the protein and nucleic acids encoding such are envisioned. Accordingly, the claimed subject matter is anticipated by the disclosure of Grotendorst et al.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grotendorst et al., U.S. Patent Number 5,408,040 in view of Brigstock et al., U.S. Patent Number 5,876,730.

The teachings of Grotendorst et al. are summarized above. Grotendorst et al. do not specifically suggest fragments comprising exons 4 and/or 5. However, it is noted that exons 4 and 5 consist of the carboxyl terminal 169 amino acids, or 48% of the CTGF polypeptide. It is common in the art to make such deletions by successively deleting portions from the ends of the molecule, often if not usually starting at the amino terminus of the protein. As Grotendorst et al. specifically suggest making functional fragments of CTGF, the Examiner finds that, using only the teachings of Grotendorst and routine experimentation (deleting portions of the protein and testing for activity), one of ordinary skill in the art would arrive at numerous species within the metes and bounds of the

rejected claims. Further, given Brigstock's disclosure that HBGF , which is residues 247-349 of CTGF has mitogenic activity, one would expect success at making such fragments, and additionally would expect that fragments comprising at least residues 247-349, which comprise the entirety of the portion of the protein encoded by exon 5, would be active. Accordingly, the invention, taken as a whole, is *prima facie* obvious over the cited prior art.

Double Patenting Rejections:

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of copending Application No. 09/461688. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to fragments of CTGF and nucleic acids encoding such. Although the two applications require different biological activities of those fragments, and are thus of different scope, there is substantial overlap in the actual fragments that are encompassed by the two sets of claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Serial Number 09/461646
Art Unit 1647

Advisory Information:

No claim is allowed.

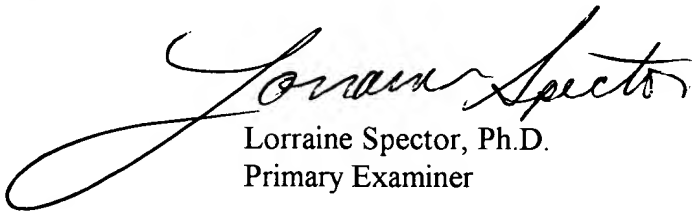
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 5:30 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703)308-4623.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 305-4242. Faxed draft or informal communications with the examiner should be directed to (703) 746-5228.



Lorraine Spector, Ph.D.
Primary Examiner

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